



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: APPARATUS AND METHOD FOR SELECTIVELY DELIVERING MEDICATION TO A WALL SECTION OF A BODY CAVITY, BLOOD VESSEL, OR THE LIKE (54) Titre: ADMINISTRATION SELECTIVE DE MEDICAMENT EN UN POINT D'UNE PAROI DE CAVITE ANATOMIQUE, DE VAISSEAU SANGUIN OU ANALOGUE, ET DISPOSITIF A CET EFFET		
(57) Abstract <p>An apparatus and method for selectively delivering a medicament to a target location of the wall of a body cavity, blood vessel, or the like, comprising a compressed hollow cylinder of permeable, expandable foam, attached to the distal end of a delivery device such as a catheter or catheter guidewire. Using the delivery device, the compressed cylinder is advanced to a target location within the body, and the compressed foam cylinder is allowed to expand so as to contact the walls of the body cavity, blood vessel, or the like, while allowing bodily fluids to freely flow through the central lumen of the cylinder. The foam cylinder is provided with means for perfusing it with a medicament so that the medicament is placed in contact with the walls of the patient's anatomy, and is also provided with means for preventing the medicament from entering the patient's bloodstream.</p> <p>(57) Abrégé La présente invention concerne un procédé et un dispositif d'administration sélective d'un médicament en un point cible de la paroi d'une cavité anatomique, d'un vaisseau sanguin ou analogue. Le dispositif comporte un cylindre creux comprimé en mousse perméable déployable fixé à l'extrémité distale d'un dispositif d'administration tel qu'un cathéter ou le fil-guide d'un cathéter. Quand on utilise le dispositif d'administration, on fait progresser le cylindre comprimé l'intérieur du corps jusqu'au point cible, puis on laisse se déployer le cylindre en mousse comprimé de façon qu'il vienne au contact des parois de la cavité anatomique, du vaisseau sanguin ou analogue, et ce, tout en laissant les fluides anatomiques circuler librement au travers de la lumière centrale du cylindre. Le cylindre de mousse est pourvu, d'une part de moyens permettant de le transfuser d'un médicament de façon que le médicament vienne au contact des parois anatomiques du patient, et d'autre part de moyens permettant d'empêcher le médicament de passer dans la circulation sanguine du patient.</p>		

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(21) International Application Number: PCT/US00/03970 (22) International Filing Date: 16 February 2000 (16.02.00) (30) Priority Data: 09/250,736 16 February 1999 (16.02.99) US (71) Applicant: SARCOS LC [US/US]: 360 Wakara Way, Salt Lake City, UT 84108 (US). (72) Inventors: JACOBSEN, Stephen, C.; 274 South 1200 East, Salt Lake City, UT 84102 (US). DAVIS, Clark, C.; 4564 Wallace Lane, Salt Lake City, UT 84117 (US). (74) Agents: MCKINNEY, David, R. et al.; Thorpe, North & Western, L.L.P., P.O. Box 1219, Sandy, UT 84091-1219 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published Without international search report and to be republished upon receipt of that report.
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Description

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APPARATUS AND METHOD FOR
SELECTIVELY DELIVERING MEDICATION TO A WALL SECTION OF A
BODY CAVITY, BLOOD VESSEL, OR THE LIKE

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BACKGROUND OF THE INVENTION

1. Field of the Invention

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This invention relates to methods for the introduction of medication to specific points in the body. More particularly, the present invention relates to an improved apparatus and method for selectively delivering medication to a specifically targeted wall section of a blood vessel, body cavity, or the like, so as to allow more accurate medication of specific ailments.

2. State of the Art

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There are a wide variety of known methods for introducing medication into the body, such as ingestion, hypodermic injection, transdermal application, inhalation, and intravenous injection. However, all of these methods result in systemic drug introduction. This is appropriate for many conditions, but not in others. In certain circumstances, it is desired to introduce a drug only at a specific site of an ailment within the body. In such cases, systemic drug introduction results in substantial over medication in order to ensure that a sufficient dosage is available at the site of the ailment. This results in the unnecessary use of excess medication, and may also exacerbate side effects.

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To address some of these problems, venous catheters and similar devices have been used to introduce medication at a specific site within a blood vessel, body cavity, or the like. The catheter is threaded through the anatomy to a point near to or at the site of a specific ailment, whereupon the medication is released from the catheter. This method, however, presents several drawbacks. In a flowing blood vessel, the medication is quickly drawn

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5 downstream from the intended application site. Thus, while
medication will be available at the desired site,
additional medication will flow system wide, presenting the
10 same drawbacks as in the case of systemic medication
5 mentioned above. In other applications, a balloon catheter
or other device may be used to stop blood flow in the
vessel to prevent the medication from being swept system
wide. However, because blood flow can only be stopped for
15 brief periods of time without causing damage to surrounding
10 tissues, this method is not satisfactory for most
applications.

20 To address these problems, devices have been developed
which attempt to place medication at a targeted site and
hold it there for an extended length of time without
15 interfering with blood flow. In some of these devices, a
drug delivery apparatus is held in place within a vessel by
25 means of barbs or other protrusions which extend out and
grab the vessel wall. These devices are undesirable
because of the trauma that they cause to body tissue.
30 Another approach of prior art devices is shown in FIG. 1.
This device utilizes a thin, inflatable coil tube, denoted
generally at 2, having impermeable webbing 4 disposed
35 between several of the coils 6 at or near the distal end 8
of the device. The distal portion 8 of the tube 2 is held
25 against the sides of the blood vessel 10 by pressurizing
the coil tube, and a medication supply tube 12 delivers
medication to the space 14 between the webbing 4 and the
40 vessel wall 10. This device may thus be held in contact
with the vessel wall for an extended period of time, while
30 blood flows essentially uninterrupted through the central
lumen 16 of the coil. However, the device of FIG. 1 also
45 presents several drawbacks. First, it does not isolate the
space 14 from the blood flow lumen 16 very well - i.e., it
leaks. Additionally, the central lumen 16 may not be large
35 enough to accommodate the necessary blood flow. Finally,

the device is complicated and expensive to manufacture.

There is thus a need for an atraumatic method of selectively introducing medication into a wall section of a body cavity, blood vessel or the like that allows the medication to remain in contact with the anatomy for an extended period of time as required, without causing trauma to body tissues, requiring the stoppage of blood flow, or resulting in needless system wide introduction of medication.

OBJECTS AND SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an atraumatic apparatus and method for selectively delivering medication to a target location of a body cavity, blood vessel, or the like that does not result in significant quantities of the medication being swept downstream and introduced into the body system wide.

It is another object of this invention to provide an apparatus and method for selectively delivering medication to a target location of a body cavity, blood vessel, or the like that does not stop the flow of blood or fluid within the anatomy in order to give the medication time to be absorbed.

It is another object of this invention to provide an apparatus and method for selectively delivering medication to a target location of a body cavity, blood vessel, or the like that allows the medication to circulate through the device so as to provide a constant concentration of the medication at the vessel/device interface.

The above and other objects are realized in an apparatus comprising a compressed hollow cylinder of permeable, expandable foam, attached to the distal end of a delivery device such as a catheter or catheter guidewire. The delivery device is for introducing the compressed cylinder into the patient's anatomy, whereby the compressed

5 foam cylinder may be advanced to a point adjacent to a
target location where medication is needed. The compressed
foam cylinder is provided with means for expanding it
within the body cavity, blood vessel, or the like, so as to
10 5 contact the walls of the body cavity, blood vessel, or the
like with its outside surface so that a medicament may be
placed in contact with the walls of the patient's anatomy,
while allowing the patient's bodily fluids to freely flow
15 through the central hollow or lumen of the cylinder. The
10 cylinder is provided with means for perfusing it with a
medicament, such as an infusion tube which extends along
the delivery device, and terminates at its distal end
20 within the foam material, whereby medicament may be
introduced into the proximal end of the infusion tube and
15 may be released from the distal end to perfuse into the
foam material. The apparatus may also be provided with a
25 second lumen for withdrawing or circulating the medicament
from or through the foam. This greatly reduces spillage if
the fluid is removed from the medicament delivery volume at
30 20 the same rate as it is infused into it. The apparatus is
also provided with means for preventing the medicament from
entering the patient's bloodstream.

In one embodiment, the foam cylinder is compressed by
35 means of a sheath disposed thereabout, and the means for
25 expanding the cylinder within the patient's anatomy
comprises one of various means for opening and pulling the
sheath off of the foam cylinder. In an alternative
40 embodiment, the sheath is soluble in water or other fluid
so that it breaks down within the patient, thereby allowing
30 the hydrophillic foam cylinder to expand. In still another
embodiment, the medicament is preloaded into the foam
45 material and released when the protective sheath is removed
from the foam cylinder.

These and other objects are also realized in a method
35 50 for selectively delivering medication to a target location

5 of a body cavity, blood vessel, or the like comprising the
steps of obtaining an apparatus for delivering said
medicament as described, introducing the apparatus into the
anatomy of the patient, directing the apparatus to an
10 5 anatomical location in need of medicament, expanding the
cylinder within the patient so as to contact the walls of
the body cavity, blood vessel, or the like with the outside
of said foam cylinder, while allowing the patient's bodily
15 fluids to freely flow through the central hollow of said
10 cylinder, delivering a medicament to the target location by
perfusing the medicament into the foam material, and
allowing the medicament impregnated foam to remain in
20 contact with the walls of the patient's body cavity, blood
vessel, or the like for sufficient time to be absorbed
15 thereby, and then removing the apparatus from the patient's
anatomy following use.

25 These and other objects are also realized in a method
for manufacturing said apparatus.

Other objects and features of the present invention
20 will be apparent to those skilled in the art, based on the
30 following description, taken in combination with the
accompanying drawings.

35 BRIEF DESCRIPTION OF THE DRAWINGS

25 FIG. 1 shows a prior art medication delivery device
comprising a helical tubular polymer coil with impermeable
webbing stretched between adjacent coils.

40 FIG. 2A shows a medication delivery device according
to the present invention which is disposed upon the end of
30 a guide wire and being directed to a target location.

FIG. 2B shows the medication delivery device of FIG.
45 2A at the target location in the process of the sheath
surrounding the foam cylinder being opened by inverting and
pulling back with the attached filaments, while the
35 cylinder expands to meet the vessel walls.

5 FIG. 2C shows a cross section of the present invention
in place at the target location, with the foam cylinder
fully expanded and contacting the vessel walls.

10 FIG. 3 shows a medication delivery device according to
5 the present invention wherein the foam cylinder is
compressed by a sheath which is opened by means of a "rip
cord" filament.

15 FIG. 4 shows a medication delivery device according to
the present invention wherein the foam cylinder is
10 compressed by a knit sheath which is opened by pulling one
cord to unravel it.

20 FIG. 5 shows a medication delivery device according to
the present invention wherein the foam cylinder is
compressed by a helically wound sheath which is opened by
15 pulling one cord to unwind the sheath.

25 FIG. 6 shows a medication delivery device according to
the present invention wherein the foam cylinder is
compressed by a sheath under vacuum pressure, and which is
opened by breaking the vacuum seal and pushing the foam
30 cylinder beyond the sheath.

 FIG. 7A shows a medication delivery device according
to the present invention wherein the foam cylinder is
formed of a compressed swelling foam, and the sheath is
35 opened by means of pushing the guidewire and foam forward
25 to puncture the end of the sheath.

 FIG. 7B shows a medication delivery device similar to
that depicted in FIG. 7A, wherein the compressed swelling
40 foam cylinder is not surrounded by a protective sheath.

 FIG. 8 shows a medication delivery device according to
30 the present invention wherein the sheath is formed of a
material which dissolves when exposed to bodily fluids such
45 as blood.

 FIG. 9A shows a cross-sectional view of a foam
cylinder having a molded-on skin to isolate the drug
35 delivery area from contact with the patient's blood flow.

5 FIG. 9B shows a cross-sectional view of a foam
cylinder having a skin that is formed by coating the inside
and end surfaces of the cylinder with a gel material which
seals the surface of the foam material.

10 5 FIG. 10A shows a cross-sectional view of a foam
cylinder which is bonded to a separately formed skin with
non-inverted end seals.

15 FIG. 10B shows a cross-sectional view of a foam
cylinder which is bonded to a separately formed skin with
10 inverted end seals.

20 FIG. 11 shows an end view of a foam cylinder according
to the present invention having a convoluted end to promote
better adaption of the foam to varying vessel diameters.

25 15 FIG. 12 shows a medication delivery device according
to the present invention having an end seal formed of a
plurality of radially oriented petals to promote better
adaption of the foam to varying vessel diameters.

30 20 FIG. 13A shows a medication delivery device according
to the present invention in its compressed state having a
helical coil within the central lumen of the compressed
foam cylinder.

35 25 FIG. 13B shows a medication delivery device according
to the present invention in its expanded state wherein the
helical coil has expanded to provide inner support to the
foam cylinder.

40 30 FIG. 14 shows a medication delivery device according
to the present invention in its expanded state having a
pair of serpentine coils connected by connecting rails to
provide inner support to the foam cylinder.

35 30 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

45 Reference will now be made to the drawings in which
the various elements of the present invention will be given
numeral designations and in which the invention will be
35 discussed so as to enable one skilled in the art to make

5 and use the invention. It is to be understood that the following description is only exemplary of the principles of the present invention, and should not be viewed as narrowing the pending claims.

10 5 Figures 2A through 2C depict one embodiment of the apparatus and general sequence of steps in the method of the present invention. FIG. 2A shows the medication delivery device, denoted generally at 20, disposed upon the distal end 24 of a delivery device 22 such as a catheter or catheter guide wire. The apparatus is being directed through a bodily opening, such as a blood vessel 26, to a target location 28 where medication is needed. It will be apparent that this invention is not limited to use in blood vessels, but can be introduced into a variety of bodily openings or cavities, such as an ear canal, nasal passages or sinuses, portions of the gastro-intestinal system, the abdominal or chest cavity, the urinary tract, reproductive organs, etc.

20 25 As depicted in FIG. 2A, the apparatus is initially tightly compressed about the end of the guidewire 22 by a sealed sheath 30, such that its size is smaller than the diameter of the vessel, and no fluid may contact the device until after the seal is broken. This configuration allows blood or other fluid flow, denoted by arrows 32, to freely continue around the device during insertion. The distal tip of the guidewire 22 or other delivery device may advantageously be provided with a radiopaque band 34 to aid the physician in directing the device to the desired target location during insertion. The medication delivery device 30 20 also includes at least one filament 36 attached to the distal end of the sheath 30, and a medication infusion tube 38.

45 50 In one embodiment, as shown in FIG. 2B, once the device 20 is guided to the target location 28, the filaments 36 are pulled from the proximal end to break the

5 seal of the sheath 30 at its distal end. Continued pulling
on the filaments 36 causes the sheath 30 to open from the
distal end and invert as it is pulled toward the proximal
end thereof, to release a compressed foam cylinder 40. The
10 5 inside surface of the sheath 31, or the outside surface of
the cylinder 42, or both, are preferably treated with a
biocompatible lubricious coating, such as a hydrophillic
material, to provide lubrication as needed to ease the
15 process of pulling back the sheath. Once pulled from
10 around the foam cylinder 40, the sheath 30 is preferably
pulled to the proximal end of the delivery device 22 by
means of the filaments 36, and entirely removed from the
20 patient's body. It will be apparent that other means of
removing the sheath may be provided, as described in detail
15 below.

25 As shown in FIG. 2B, once the sheath 30 is removed,
the cylinder 40 expands to meet the vessel walls 26. Once
expanded, the structure of the apparatus 20 becomes more
apparent. Contained within the sheath 30 is a hollow foam
30 20 cylinder 40, formed of a soft, spongy, open cell material
which can hold medication. The cylinder 40 may be formed
to accommodate medicines in various forms, such as liquids,
powders, or pellets. It is preferably formed of a urethane
35 foam material which may be tightly compressed, but will
25 expand to its original shape and size when the compressive
force of the sheath is released. Alternatively, the
cylinder 40 may be formed of a hydrophillic foam material
40 that expands to much more than its original size when in an
aqueous solution, such as blood. Alternatively, the
30 cylinder 40 may be constructed of cellulose or other foam
that can be dried in a compressed condition, and will
45 remain in that shape until it is wetted again. As still
another alternative, the cylinder 40 may be formed of a
urethane or other foam material, which is then provided
35 with a coating to change the surface properties of the

5 foam. For example, a coating which makes the ordinary
urethane hydrophilic so as to expand in an aqueous
10 solution may be added. Alternatively, coatings which
change the structural properties of the foam may also be
5 provided, such as a coating which makes the foam cylinder
stiffer.

15 From FIGs. 2B and 2C some other structure of the
present device also becomes visible. The distal end of the
delivery device 22 is provided with tethers 44 which
10 connect the tip of the delivery device to the distal end of
the foam cylinder 40. The proximal end of the cylinder is
also connected to the delivery device 22 by tethers 45 as
20 shown in FIG. 2C. These tethers advantageously allow the
expanded foam cylinder 40 to remain attached to the
15 delivery device 22, while allowing it to expand away from
it. This provides a central lumen 46 for uninterrupted
25 blood or other fluid flow, denoted by arrows 32, while
still providing a strong connection to the delivery device.
This configuration advantageously allows the physician or
30 other user to manipulate the drug delivery device if needed
after it has expanded in the vasculature, and also
facilitates removal of the device as described below. It
35 will be apparent that, as oppositely oriented thin tension
members, the tethers 44 and 45 must be strong enough to
25 connect the foam cylinder 40 to the guidewire 22 in a
pressurized, flowing environment, and also in anticipation
40 of friction with the side walls of the vessel.

Once the sheath is entirely removed, the cylinder 40
expands to press against the vessel walls, and deliver its
30 medication, while allowing blood to flow through the
central lumen 46. FIG. 2C provides a cross section of the
45 cylinder 40 and related structure when in place at the
target location, with the foam cylinder fully expanded and
contacting the vessel walls. In this view the tethers 44
35 and 45 are clearly visible in their extended orientation.

5 The foam cylinder 40 is preferably in the shape of a hollow
cylinder, having an outside medication delivery surface 42
for contact with the wall of a body cavity, blood vessel or
the like, an inside surface 48 proximal to the guidewire
10 5 22, and annular end surfaces 50. As shown in FIG. 2C, the
inside surface 48 and annular end surfaces 50 are
preferably coated with a nonporous skin 52, which prevents
outflow of the medication except toward the vessel walls.
15 This configuration provides one of the great advantages of
the present invention by keeping the medication in contact
10 with the delivery site in an atraumatic manner, but
preventing it from entering the blood and flowing
20 downstream. A small portion of the outside surface 42
immediately adjacent to the annular end surfaces 50 may
15 also be provided with this skin 52 so as to ensure a
positive seal between the foam cylinder and the vessel
25 wall. There are a number of methods of forming the skin
52, which will be described in more detail below.

As depicted in FIG. 2C, medication is preferably
30 20 provided to the foam cylinder by means of an infusion tube
38, which follows the delivery device 22 and delivers the
medication directly into the foam cylinder 40. It will be
apparent that more than one infusion tube 38 may be
35 provided, or the infusion tube may have multiple openings
25 or delivery points into the foam material to provide more
uniform saturation of the foam material with the
medication. Additionally, a pair of infusion tubes may be
40 advantageously provided to allow medication to be
introduced through one tube and extracted through the
30 other, thus allowing medication to be circulated through
the foam material for more complete and uniform exposure of
45 the body cavity wall to the medication. Alternatively, the
foam material or the skin of the foam material may be pre-
loaded with a medication, which is naturally absorbed by
35 the wall of the blood vessel or the like when the foam

5 cylinder is placed in contact with it. Such medications
may be provided in the form of powders, pellets, or liquid
as described above. It will be apparent that pre-loading
10 of the medication avoids the need for an infusion tube,
5 which helps reduce the overall size of the apparatus,
making introduction into the patient's anatomy easier and
less intrusive. A preloaded medication is advantageously
15 protected from contact with and dispersal into the
bloodstream during introduction of the device by the sealed
10 sheath 30.

Because of its soft, atraumatic design and
20 construction, once the medication delivery process is
complete, the entire apparatus 20 can be removed simply by
pulling on the proximal end of the guidewire 22 to remove
15 it from the patient. Because the tethers 44 and 45 are
strong enough to withstand the forces created by friction
25 with the sidewalls of the vessel 26, the apparatus cannot
become detached from the delivery device and lodge within
the patient. Alternatively, a hollow catheter 56 with an
30 openable mouth 58 may be threaded over the guidewire 22,
and the guidewire 22 and drug delivery apparatus 20 may be
pulled inside the catheter and removed from the patient.
This method provides the advantage that the catheter 56 may
35 remain in place for subsequent procedures if desired.
25 Alternatively or additionally, the catheter 56 may be
provided with a grabbing device, such as spring loaded
protrusions 60 or a bag (not shown), to capture the foam
40 device 20 and pull it into the mouth of the catheter 56.
It will be apparent that the medication delivery apparatus
30 20 may also be initially introduced into the patient by
means of such a catheter 56, rather than a guidewire 22.
45 In such an alternative configuration, the catheter 56 could
contain a guidewire within, and the apparatus 20 could be
removed from the patient by removing the catheter along the
35 guidewire, leaving the guidewire in place to facilitate

5 subsequent procedures.

As noted above, there are various means of opening and removing the sheath 30. FIG. 3 shows a medication delivery device according to the present invention wherein the foam
10 5 cylinder is compressed by a sheath 30a which is opened by means of a "rip cord" filament 64. This sheath 30a is provided with a longitudinally oriented weakened area 66. The "rip-cord" filament 64 is attached to either the
15 proximal end of the foam cylinder 40, or to the guidewire 22 near the proximal end of the cylinder, and is disposed between the outer surface of the foam cylinder 42 and the inner surface 31a of the sheath 30a in the weakened region.
20 The "rip cord" filament 64 then passes through the end seal of the sheath at the distal end, and doubles back along the delivery device to its proximal end, where a user may grasp and pull it. Initial pulling on the "rip cord" causes the
25 end seal to break, and continued pulling cuts the sheath along the weakened region. Additional filaments 36 are advantageously provided to allow the sheath to be inverted and pulled from around the cylinder and out of the patient
30 in a manner similar to that described above.

The longitudinally oriented weakened region 66 of the sheath 30a may be formed in many different ways. The
35 weakened region 66 may comprise a line of full depth perforations, partial depth perforations, a thinned
25 section, or any other method which will allow the "rip cord" filament 64 to cut the sheath 30a.

FIG. 4 shows an alternative sheath configuration of the present invention wherein the foam cylinder 40 is
40 compressed by a knit sheath 70. This sheath is formed of a single cord 72 which is knit or sewn into a tubular
30 configuration having sufficient strength to hold the cylinder 40 in its compressed configuration. At the distal end of the sheath, the end of the single cord 72 doubles
45 back along the delivery device 22 to its proximal end,
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5 where a user may grasp and pull it. When the user does so,
the knit sheath 70 begins to unravel, progressively
allowing the cylinder 40 to expand to fill the body cavity,
10 and allowing the cord 72 to be completely removed from the
5 patient.

FIG. 5 shows another alternative embodiment of the
medication delivery device of the present invention wherein
the foam cylinder 40 is compressed by a helically wound
15 sheath 74. Like the knit sheath of FIG. 4, the helically
10 wound sheath 74 is preferably formed of a single cord 76,
which doubles back from its distal end along the delivery
device 22 to the proximal end thereof, where a user may
grasp and pull it. When the user does so, the helically
20 wound sheath 74 begins to unwind, progressively allowing
15 the cylinder 40 to expand to fill the body cavity, and
allowing the helical cord 76 to be completely removed from
25 the patient. It will be apparent that in the embodiments
of both FIG. 4 and FIG. 5, the compressed cylinder is not
sealed from contact with bodily fluids prior to release of
30 the sheath, unlike the other embodiments of the present
20 invention.

FIG. 6 shows another embodiment of the present
invention wherein the foam cylinder 40 is held in a sheath
35 30b which is compressed by means of vacuum pressure. The
25 vacuum pressure may be applied by any suitable method, such
as by a vacuum tube 78 connecting the space inside the
sheath to a vacuum pump or syringe (not shown) outside of
40 the patient. To open the sheath and expose the delivery
device 20, the internal vacuum is released, allowing the
30 closed distal end 80 of the sheath 30b to open. The foam
cylinder 40 may then be pushed through the open end 80 of
45 the sheath, to allow it to expand in the body cavity.
Filaments 36 are preferably embedded in the proximal end of
the sheath 30b to allow it to be pulled backward and out of
50 the patient while the foam cylinder 40 is pushed forward by

5 the guidewire 22 or other delivery device. It will be
apparent that after release of the vacuum and expansion of
the foam cylinder 40, the vacuum tube 78 may advantageously
10 be used as an infusion tube to provide the medication to
5 the foam cylinder.

FIG. 7A shows a medication delivery device according
to the present invention wherein the foam cylinder 40a is
formed of a compressed swelling foam, and the foam cylinder
15 40a is formed of a swelling foam material. It will be
10 apparent to one skilled in the art that the foam could be a
non-swelling foam which is impregnated with a hydrophillic
material that absorbs water from the blood or other bodily
20 fluid, and expands to the required therapeutic size. In
the embodiment of FIG. 7A, the foam cylinder 40a is
15 protected from liquid, until release is desired, by a
protective sealed sheath 30c. A lumen in the guidewire 22
25 or a separate tube 82 operates as an infusion tube to
supply medicament to the foam tube 40a.

The sheath 30c is opened by means of pushing the
20 guidewire 22 and foam 40a forward to puncture the distal
30 end 84 of the sheath. The sheath 30c is prevented from
forward motion by one or more filaments 36 that run through
the catheter and out its proximal end, and which allow the
35 sheath 30c to be retracted and removed from the patient so
25 that the cylinder 40 may expand. The distal tip of the
guidewire 22 may be advantageously formed in a pointed
configuration so as to more easily puncture the seal at the
40 distal end of the sheath.

FIG. 7B shows a medication delivery device similar to
30 that depicted in FIG. 7A, wherein the compressed, swelling
foam cylinder 40a is not surrounded by a protective sheath,
45 but is simply introduced into the patient in its exposed
condition. In this embodiment, the cylinder 40a is
designed to swell at a rate such that it may be introduced
35 into the patient and directed to the target location before
50

5 it swells to its therapeutic size and causes excessive
friction with the patient's internal anatomy. As with the
above described embodiments, the cylinder 40a is provided
10 with an infusion tube 38, or alternatively, may be
5 preloaded with a medication. The cylinder is shown
attached to the delivery device via tethers 44 and 45, such
that it may be removed following the medication delivery
15 procedure. However, retraction filaments 36 may be
alternatively provided, which allow the cylinder to be
20 removed independently of the delivery device.

The embodiment of FIG. 7B also highlights another
20 alternative configuration of the present invention. With
the foam cylinder 40a attached to the end of the delivery
device 22 without a compressive outer sheath, it will be
15 apparent that some method of attachment between the
delivery device and the cylinder is needed to ensure that
25 the cylinder is firmly attached as it is being advanced
into the patient. While the distal tethers 44 could
conceivably perform this function, this would be less than
30 satisfactory. To solve this problem, the foam cylinder 40a
may be attached to the distal end of the delivery device 22
by means of a soluble bonding agent disposed between the
35 inside surface 48 of the foam cylinder and the outside
surface of the distal end of the delivery device. This
25 bonding agent is configured to dissolve in the patient's
internal environment, allowing the foam cylinder to expand
away from the delivery device to contact the walls of the
40 body cavity, blood vessel, etc. It will be apparent that
the bonding agent between the inside surface 48 of the foam
30 cylinder and the outside surface of the delivery device
must be configured to dissolve at a rate that is somewhat
45 faster than the rate of expansion of the expanding foam
cylinder to prevent the foam cylinder from expanding to
contact the walls of the body cavity while still connected
35 to the delivery device, resulting in total blockage of the

5 body cavity or blood vessel. It will also be apparent to
one of skill in the art that the use of a soluble bonding
agent between the foam cylinder and the delivery device
could advantageously be employed in many of the other
10 5 embodiments of the present invention described herein.

FIG. 8 shows another embodiment of the present
invention wherein the sheath 30d is formed of a soluble
biocompatible material which will dissolve when exposed to
15 bodily fluids such as blood, water, etc. In this
10 embodiment, the sheath material may be formulated and
formed so as to dissolve at any desired rate, allowing the
user adequate time to position the device 20 within the
20 patient. In this embodiment the foam material may comprise
the conventional compressed urethane or other foam
15 discussed above, or may be the swelling foam, which is
protected from liquid until the sheath dissolves. It will
25 also be apparent that the drug delivery device may be pre-
loaded with medication as discussed above, or may comprise
an infusion tube 38 to deliver medication to the cylinder.

20 FIG. 9A shows a cross-sectional view of a foam
cylinder 40 showing the skin 52 which isolates the drug
delivery area from contact with the patient's blood flow.
This view clearly shows the outside surface 42 of the
35 sheath, which is intended to contact with the wall of the
25 body cavity, blood vessel or the like, so as to deliver the
medication. The inside surface 48 and annular end surfaces
50 are coated with a nonporous skin 52, which prevents
40 outflow of the medication, except toward the cavity walls.
The skin 52 may be formed of latex or cellulose, but
30 urethane is preferred. In the preferred embodiment, a
small area 54 of the outside surface 42 immediately
45 adjacent to the annular end surfaces 50 is also coated with
the skin so as to provide a better seal between the
cylinder 40 and the cavity wall.

35 In the embodiment of FIG. 9A, the skin 52 is molded

5 onto the foam cylinder 40. This may be done in several
ways. For example, the foam cylinder may be formed by an
extrusion or molding process which forms a skin on the
10 inside diameter of the cylinder. Then, a skin may be
5 bonded to the annular end surfaces, or the annular end
surfaces may be coated with a gel that swells into the
surface cavities of the foam and seals it. Alternatively,
15 the foam cylinder may be formed by injection of foam
material into a mold already having a skin formed therein.
10 Yet another alternative is to form the foam cylinder
without a skin, and then bond a separately made skin onto
it. This may be done by dip coating a formed skin with
20 foam material. Alternatively, it may be done by dip
coating a formed foam cylinder into skin material. As yet
15 another alternative, the skin may be formed on the surface
of a separately formed foam tube by inverting a formed foam
25 cylinder to expose the inside diameter, spray coating a
skin material thereon, then re-inverting it. Finally, the
skin may be applied by compressing the cylinder, freezing
30 it, then die cutting it to form the skin

FIG. 9B shows a cross-sectional view of a foam
cylinder 40 having a skin 110 that is formed by coating the
inside and end surfaces 48 and 50 of the cylinder with a
35 gel material which seals the surface of the foam material.
25 This coating may be applied by any of the methods described
above. This gel material penetrates the open cell
structure of the surface of the foam, and forms a water
40 tight barrier which prevents the medication from escaping
from the foam into the bloodstream. Urethane hydrogel is
30 presently preferred as this gel material to form the
coating, but any material that is very flexible and swells
45 in contact with water and bonds to the foam will perform
properly according to the objects of this invention.

In any of the embodiments of this invention, the outer
35 surface 42 of the foam cylinder may be coated with a porous

5 outer skin 112, as shown in FIG. 9B. This coating may be
formed of hydrophillic urethane or silicone rubber, and
acts to reduce thrombus formation around the foam.

10 Alternatively, the porous outer skin 112 may be provided
5 with a plurality of check valves 114 which allow medicament
to flow out, but prevent fluids from flowing into the foam
material. These check valves could be formed as small
flaps in a hydrophillic urethane membrane that forms the
15 outer skin 112.

10 There are several ways that a foam cylinder may be
bonded to a separately formed skin, one of which is
depicted in FIGs. 10A and 10B. FIG. 10A shows a cross-
20 sectional view of a foam cylinder 40 which is bonded to a
separately formed skin 84 with non-inverted end seals 86.
15 The skin 84 is formed first, then the foam material is
placed thereon to form a cylinder. The non-inverted end
25 seals 86 have slits 88 to facilitate inversion over the
ends of the foam cylinder 40, and to accommodate a range of
vessel diameters. Once the foam material is in place, the
20 end seals may be inverted to wrap around the ends of the
cylinder, as shown in FIG. 10B. Tethers 90 may be provided
30 to attach opposing edges of inverted end seals to prevent
them from uninverting. Alternatively, the end seals may be
bonded to the foam cylinder 40 in the inverted position by
35 means of a biocompatible bonding agent.

FIG. 11 shows an end view of a foam cylinder 40
40 according to the present invention having a convoluted or
corrugated end 92. This configuration promotes better
adaptation of the foam cylinder 40 to varying diameters and
30 irregularities of the vessel 26 because the skinned surface
expands and contracts in a more coordinated fashion than it
45 would without the convolutions. In one embodiment the
convolutions 92 may be biased against the vessel walls by
means of a spring disposed within the distal end of the
35 foam cylinder. Alternatively, FIG. 12 shows the medication

5 delivery device of the present invention having a non-
inverted end seal 100 formed of a plurality of radially
oriented petal-shaped lips 102. This configuration also
10 promotes adaptation of the foam cylinder 40 to varying
5 diameters and irregularities of the vessel 26. The petals
102 may expand non-uniformly to contact the walls of the
vessel, sealing the edges of the cylinder to prevent
15 migration of the medication into the bloodstream. This
embodiment may also be spring loaded, or may rely solely on
10 the resiliency of the material from which the petal-shaped
lips are formed for biasing against the vessel walls. In
20 any of the embodiments of this invention, including those
of FIG. 11 or FIG. 12, the end surfaces of the foam
cylinder or the lips may be coated with a hydrophillic gel
15 which occludes the foam material and promotes a better seal
between the apparatus and the vessel walls while preventing
25 leakage of the medicament from the foam material. FIG. 9B
and FIG. 12 show the typical placement of this hydrophillic
gel 115 on the end surfaces of the foam cylinder 40 or
30 petal shaped lips 102 so as to enhance the seal between the
device and the vessel wall 26.

In lieu of or in addition to the expansive force of
the foam cylinder, the medication delivery device of this
35 invention may be provided with inner support means for
25 providing a force for biasing the foam cylinder against the
walls of the body cavity. This may be done in several
ways. In the embodiment of FIG. 9A and FIG. 9B, the skin
40 48 forming the central lumen 46 of the device and the end
surfaces 52 may be formed of a resilient material which,
30 after the release of the compressive force of the outer
sheath or similar means for compressing the foam cylinder
45 40, will expand to resume its uncompressed shape. This
expansion will help provide cylindrical support to the
device.

35 Alternatively, other means of providing inner support

5 to the cylinder may be provided. One such alternative is
shown in FIGs. 13A and 13B, wherein a helical coil 120 of
thin superelastic ribbon is disposed within the central
10 5 lumen 46 of the foam cylinder 40. In FIG. 13A, when the
foam cylinder 40 is compressed by a sheath 30, the helical
coil 120 is also compressed within the lumen 46. Once the
compressive force of the sheath or other means is released,
15 the foam cylinder 40 expands, as shown in FIG. 13B,
assisted in part by the coil 120 which also expands,
10 pushing on the interior surface of the central lumen 46.
The helical coil 120 may be advantageously configured to be
pulled into the lumen of a catheter 56, or alternatively, a
20 lumen formed in the delivery device 22 itself. This will
allow a user of the device to remove the inner support
15 means following proper placement and expansion of the foam
cylinder at the intended site of medication delivery.

25 FIG. 14 depicts another alternative means of providing
an inner support for the foam cylinder. In this
embodiment, the cylinder 40 is provided with a pair of
20 serpentine coils 130 which expand radially and press
against the inside surface 48 of the lumen 46. The coils
30 130 are connected by a plurality of longitudinal connecting
rails 132 which connect adjacent nodes of the opposing
coils 130. The rails 132 are preferably oriented parallel
35 to the delivery device as shown, and are drawn away from
the delivery device 22 as the serpentine coils expand.
Like the embodiment of FIG. 13, when the foam cylinder 40
40 is compressed by a sheath or other means, the serpentine
coils 130 are also compressed within the lumen 46, and held
30 tightly around the delivery device 22. Once the
compressive force is released, however, the foam cylinder
45 40 expands, assisted by the serpentine coils 130 and
connecting rails 132, which also expand, pushing on the
interior surface of the central lumen 46. It will be
35 apparent that instead of a pair of serpentine coils

5 connected by connecting rails, a plurality of unconnected
serpentine coils could be provided along the length of the
central lumen, or alternatively, a single serpentine coil
10 5 which extends the length of the lumen could be provided to
accomplish the same ends. Also as in the embodiment of
FIG. 13, the serpentine coils 130 and connecting rails 132
may be advantageously configured to be pulled into the
15 lumen of a catheter 56, allowing a user of the device to
remove the inner support means following proper placement
10 and expansion of the foam cylinder at the intended site of
medication delivery.

20 It is to be understood that the above-described
arrangements are only illustrative of the application of
the principles of the present invention. Numerous
15 25 modifications and alternative arrangements may be devised
by those skilled in the art without departing from the
spirit and scope of the present invention and the appended
claims are intended to cover such modifications and
arrangements.

Claims

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CLAIMS

What is claimed is:

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1. Apparatus for selectively delivering a medicament to a target location of a wall of a patient's body cavity, blood vessel, or the like, comprising:

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a compressible and expandable hollow cylinder of permeable foam, said cylinder having an outer surface, a central lumen, and proximal and distal end surfaces;

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delivery means for introducing the cylinder into a patient's body cavity, blood vessel, or the like, said delivery device having a proximal end and a distal end, and said cylinder being attached near the distal end of said delivery means to enable advancement of the cylinder into the patient's anatomy for placement adjacent to a target location;

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means for expanding the cylinder within the body cavity, blood vessel, or the like, so as to contact the walls thereof with the outer surface of the cylinder when said cylinder has been placed adjacent to the target location, thereby allowing the patient's bodily fluids to freely flow through the central lumen of the cylinder; and

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means for perfusing said cylinder with a medicament whereby the medicament is placed in contact with said walls.

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2. Apparatus as described in claim 1 wherein the foam cylinder is formed of a material selected from the group comprising urethane, hydrophilic materials that expand in aqueous solutions.

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3. Apparatus as described in claim 3 further

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5 comprising a coating applied to the outer surface of said
cylinder, said coating being selected from the group
comprising a hydrophillic coating, an anti-thrombogenic
10 5 agent, a permeable anti-thrombogenic membrane, a coating
which mechanically stiffens the cylinder, and a coating
which forms an impermeable seal on the surface of said foam
material.

15 4. Apparatus as described in claim 1, further
10 comprising a porous skin formed on the outer surface of
said foam cylinder.

20 5. Apparatus as described in claim 4, further
comprising check valves formed in said porous skin to allow
15 medicament to flow out, but prevent fluids from flowing
into the foam material.

25 6. Apparatus as described in claim 5, wherein said
porous skin is formed of a hydrophillic urethane material,
30 20 and said check valves comprise a plurality of flaps formed
in said skin.

35 7. Apparatus as described in claim 1 wherein the
delivery device is selected from the group comprising a
25 catheter and a catheter guidewire.

40 8. Apparatus as described in claim 7 wherein the
means of attachment of said foam cylinder to the distal end
of said delivery device comprises at least one tether
30 connected between the distal end of the foam cylinder and
the distal end of the delivery device, and at least one
45 tether connected between the proximal end of the foam
cylinder and the delivery device, whereby the compressed
foam cylinder may be advanced through the patient's anatomy
35 as the delivery device is so advanced.

5 9. Apparatus as described in claim 7 wherein said
foam cylinder is attached to the distal end of said
delivery device by means of a bonding agent which is
soluble in bodily fluids.

10 5 10. Apparatus as described in claim 7 wherein the
delivery device is a catheter having an opening at its
distal end, said distal opening terminating within the foam
15 material, whereby the means for perfusing said cylinder
20 with a medicament comprises introducing a medicament into
said catheter and allowing said medicament to flow into
said foam material.

25 15 11. Apparatus as described in claim 1 wherein the
means for perfusing said cylinder with a medicament
comprises at least one hollow tube extending the length of
25 the delivery device, said at least one tube having a first
end which extends outside the patient and is configured to
receive the medicament, and a second end which extends into
30 the foam material, whereby medicament may be selectively
introduced into said first end and thereby flow from said
second end to perfuse said foam cylinder, so as to be
brought into contact with the walls of said body cavity,
35 blood vessel, or the like.

40 25 12. Apparatus as described in claim 11 wherein the
means for perfusing said cylinder with a medicament
comprises two hollow tubes which extend the length of the
40 delivery device, such that the medicament may be introduced
30 into the first end of the first tube to perfuse said foam
cylinder, and may be subsequently drawn from said foam
45 cylinder into the second end of the second tube such that
the medicament is circulated through said foam material to
reduce spillage of medicament into the bloodstream.

5 13. Apparatus as described in claim 11 wherein said
at least one tube comprises a plurality of perfusion ports
in the second end thereof so as to provide multiple
medicament entry points into said foam material.

10 5 14. Apparatus as described in claim 1 wherein the
means for perfusing said cylinder with a medicament
comprises preloading a drug into the foam material, said
15 drug being in a form selected from the group comprising
10 powder, pellets, and liquid.

20 15. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises a soluble sheath
tightly disposed around said compressed foam cylinder and
15 having a sealed distal end, said sheath configured to
dissolve after contact with bodily fluids, to thereby allow
25 said compressed cylinder to expand.

30 20 16. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises:
a sheath tightly disposed around said compressed foam
cylinder and having a sealed distal end; and
means for breaking the seal of the distal end, and
35 inverting and pulling said sheath toward the
25 proximal end of said delivery device, so as to
remove it from around said compressed cylinder,
to thereby allow said compressed cylinder to
expand.

40 30 17. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises:
45 a sheath formed of knit filaments;
at least one filament of the sheath extending from the
distal end of said knit sheath along the delivery
35 device to the proximal end thereof, whereby an

5 operator may pull said filament, causing the knit
sheath to unravel and thereby allow said
compressed cylinder to expand.

10 5 18. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises:
a sheath formed of at least one helically wrapped
filament;
15 at least one filament of the helically wrapped sheath
10 extending from the distal end of said sheath
along the delivery device to the proximal end
thereof, whereby an operator may pull said
20 filament, causing the helical sheath to unwrap
and thereby allow said compressed cylinder to
15 expand.

25 19. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises:
a sheath formed of braided filaments in tension;
20 at least one filament of the braided sheath extending
30 from the distal end of said sheath along the
delivery device to the proximal end thereof,
whereby an operator may pull said filament,
35 causing the tension in said braided sheath to be
25 released and thereby allow said compressed
cylinder to expand.

40 20. Apparatus as described in claim 1 wherein the
means for expanding the cylinder comprises:
30 a sheath disposed around said compressed foam
cylinder, said sheath having a sealed distal end
45 and being placed under vacuum pressure so as to
tightly squeeze the foam cylinder;
means for opening the sealed distal end of said
35 sheath; and
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5 means for releasing said vacuum pressure and pushing
said foam cylinder through said distal end to
thereby allow said compressed cylinder to emerge
from said sheath and expand within the patient's
10 5 anatomy.

21. Apparatus as described in claim 20 wherein the
means for opening the sealed distal end of the sheath
15 comprises means for puncturing the sealed distal end of
10 said sheath so as to cause it to open, said means for
puncturing being contained within said sheath.

22. Apparatus as described in claim 1 wherein the
foam cylinder has time dependent swelling characteristics,
15 and the means for expanding the cylinder comprises
introducing the cylinder into the anatomy and advancing it
25 to the target location before the cylinder swells to its
required therapeutic size.

23. Apparatus as described in claim 2 wherein the
means for opening the sealed distal end of the sheath
30 comprises:
a protrusion extending from the distal end of said
35 delivery device, said protrusion being contained
25 within said sheath;
means for extending said protrusion toward the distal
end of said sheath so as to puncture the sealed
40 distal end of said sheath and cause it to open;
and
30 means for pushing said foam cylinder through the open
distal end of said sheath and advancing said
45 cylinder into the patient's anatomy.

24. Apparatus as described in claim 3 wherein said
35 anti-thrombogenic agent is selected from the group

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5 comprising heparin and hydrophillic coatings.

10 25. Apparatus as described in claim 3 wherein the anti-thrombogenic membrane comprises a material selected from the group comprising a hydrophillic polymer film, a microporous film, and laser cut holes in a polymer film.

15 26. Apparatus as described in claim 1, further comprising means for preventing the medicament from entering the flow of the patient's bodily fluids.

20 27. Apparatus as described in claim 26, wherein the means for preventing the medicament from entering the flow of the patient's bodily fluids comprises an impermeable membrane covering at least the central lumen and the end surfaces of the foam cylinder, so as to prevent the medicament from leaking from the foam cylinder.

30 28. Apparatus as described in claim 27, wherein the portion of said impermeable membrane which covers the end surfaces of the foam cylinder extends onto and covers a portion of the outer surface of said cylinder near each end surface.

35 29. Apparatus as described in claim 1, further comprising inner support means disposed within the central lumen of the compressed foam cylinder so as to provide cylindrical support to the cylinder when in its expanded state.

40 30. Apparatus as described in claim 29 wherein said inner support means is selected from the group comprising a resilient skin covering at least the central lumen and the end surfaces of the foam cylinder, a helical coil of superelastic ribbon which expands when the foam cylinder is

5 allowed to expand, at least one resilient serpentine coil
which expands when the foam cylinder is allowed to expand,

10 31. Apparatus as described in claim 29 wherein the
5 inner support means is configured to be pulled into a lumen
formed in the delivery device for removal from the patient.

15 32. Apparatus as described in claim 30 wherein said
inner support means comprises two serpentine coils, one
10 disposed at the proximal end of said foam cylinder, and one
disposed at the distal end of said foam cylinder, said
serpentine coils being connected by a plurality of elongate
20 rails disposed parallel to the delivery device.

15 33. Apparatus as described in claim 32 wherein the
serpentine coils with connecting rails are configured to be
25 pulled into a lumen formed in the delivery device for
removal from the patient.

30 34. Apparatus as described in claim 1 wherein the
delivery device comprises a catheter having at least one
openable mouth at its distal end, into which the foam
cylinder may be retracted for removal from the patient
35 following use.

25 35. Apparatus as described in claim 1 wherein the end
surfaces of the compressed foam cylinder comprise resilient
40 lips configured to provide a seal between the end surfaces
of the foam cylinder and an irregularly shaped body cavity.

30 36. Apparatus as described in claim 35 wherein said
lips are selected from the group comprising convoluted
45 conical lips, cylindrical lips, petal shaped lips, and
hydrophillic lips which swell when hydrated.

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- 5 37. Apparatus as described in claim 36 wherein said
lips are spring loaded by means selected from the group
comprising a serpentine spring, and a ring spring.
- 10 5 38. Apparatus as described in claim 35, further
comprising a hydrophilic gel disposed over the outer
surface of said resilient lips so as to enhance said seal.
- 15 39. Apparatus as described in claim 35 further
10 comprising a hydrophilic gel perfused into the foam
material to occlude the foam cells when hydrated.
- 20 40. An apparatus for selectively delivering a
medicament to a target location of the wall of a patient's
15 body cavity, blood vessel, or the like, comprising:
a hollow cylinder of permeable, expandable foam, said
25 cylinder having an outer surface, a central
lumen, and proximal and distal end surfaces,
said cylinder held in a compressed configuration
20 by means of a sealed sheath disposed thereabout,
30 and formed of a material which expands when in
contact with bodily fluids;
a delivery device for introducing the compressed
35 cylinder into a patient's body cavity, blood
25 vessel, or the like, said delivery device having
a proximal end and a distal end, said compressed
foam cylinder being attached near the distal end
40 of said delivery device, whereby the compressed
foam cylinder may be advanced into a patient's
30 anatomy and placed adjacent to the target
location;
45 means for breaking the seal and removing the sheath
from about the cylinder, thereby allowing the
cylinder to expand within the body cavity, blood
35 vessel, or the like when it has been placed
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5 adjacent to the target location, so as to contact
the walls of the body cavity, blood vessel, or
the like with the outer surface of said foam
cylinder, allowing the patient's bodily fluids to
10 5 freely flow through the central lumen of said
cylinder;

means for providing a medicament to the foam cylinder
such that the medicament is placed in contact
15 with said walls; and

10 means for preventing the medicament from passing into
the central lumen or through the end surfaces of
said cylinder so as to enter the flow of the
20 patient's bodily fluids.

15 41. A method for selectively delivering a medicament
to a target location of the wall of a body cavity, blood
25 vessel, or the like, comprising the steps of:

a) obtaining an apparatus comprising:
a compressed hollow cylinder of permeable,
20 expandable foam, said cylinder having an
30 outer surface, a central lumen, and proximal
and distal end surfaces;

a delivery device for introducing the compressed
35 cylinder into a patient's body cavity, blood
25 vessel, or the like, said delivery device
having a proximal end and a distal end, said
foam cylinder being attached near the distal
40 end of said delivery device, whereby the
compressed foam cylinder may be placed
30 adjacent to the target location;

means for expanding the cylinder within the body
45 cavity, blood vessel, or the like, when it
has been placed adjacent to the target
location so as to contact the walls of the
35 body cavity, blood vessel, or the like with

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5 the outer surface of said foam cylinder,
allowing the patient's bodily fluids to
freely flow through the central lumen of
said cylinder;

10 5 means for perfusing said cylinder with a
medicament comprising at least one hollow
tube extending at least the length of the
delivery device, said at least one tube
15 having a first end which extends outside the
patient and is configured to receive a
medicament, and a second end which extends
into the foam material, whereby medicament
20 may be selectively introduced into said
first end and thereby flow from said second
end into the foam material, thereby placing
the medicament in contact with said walls;

25 means for preventing the medicament from entering
the flow of the patient's bodily fluids;

30 20 b) introducing said apparatus into the anatomy of the
patient;

35 25 c) directing said apparatus to an anatomical location
in need of medicament;

40 25 d) expanding the cylinder within the patient so as to
contact the walls of the body cavity, blood
vessel, or the like with the outer surface of
said foam cylinder, while allowing the patient's
bodily fluids to freely flow through the central
lumen of said cylinder;

45 30 e) delivering a medicament to the target location by
introducing the medicament into the first end of
the hollow tube, such that the medicament flows
out of the second end of said tube into the foam
material, and is held in contact with the walls
of the patient's body cavity, blood vessel, or
35 the like for sufficient time to be absorbed

- 5 thereby; and
- f) removing the apparatus from the patient's anatomy
 following use.
- 10 5 42. The method of claim 41 further comprising the
 step of coating said cylinder with an anti-thrombogenic
 agent before introducing said apparatus into the anatomy of
 the patient.
- 15 10 43. The method of claim 41 wherein the step of
 expanding said cylinder within the patient further
 comprises the step of removing a sheath which surrounds the
20 compressed cylinder, so as to allow the cylinder to expand
 within the patient's anatomy.
- 15 15 44. The method of claim 41 wherein the step of
 expanding said cylinder within the patient further
25 comprises the step of allowing the cylinder to swell when
 contacted by bodily fluids.
- 20 20 45. The method of claim 41 wherein the step of
 removing the apparatus from the patient's anatomy following
30 use further comprises retracting said cylinder into the
 lumen of a catheter having an openable mouth in the distal
35 25 end thereof.
- 40 46. The method of claim 41 wherein the step of
 removing the apparatus from the patient's anatomy following
 use further comprises capturing said apparatus with a
30 capturing device disposed at the distal end of the delivery
 device.
- 45 47. A method of manufacturing an apparatus for
 selectively delivering a medicament to a target location of
35 the wall of a body cavity, blood vessel, or the like,
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- 5 comprising the steps of:
- 10 5 g) forming a hollow cylinder of permeable, expandable foam, said cylinder having an outer surface, a central lumen, and proximal and distal end surfaces, and being formed of a material which expands when in contact with bodily fluids;
 - 15 10 h) forming a skin on at least the central lumen and end surfaces of said cylinder for preventing the medicament from entering the flow of the patient's bodily fluids;
 - 20 15 i) attaching the cylinder to the distal end of a delivery device for introducing the compressed cylinder into a patient's body cavity, blood vessel, or the like, said delivery device having a proximal end and a distal end, so that the foam cylinder may be advanced into a patient's anatomy and placed adjacent to the target location by advancing the delivery device into the patient's anatomy;
 - 25 20 j) attaching to the cylinder means for providing a medicament to the foam cylinder such that the medicament may be perfused into said foam material;
 - 30 25 k) forming a sheath about the outer surface of said cylinder, whereby the foam cylinder is tightly compressed upon the distal end of said delivery device, and sealed from external contact; and
 - 35 40 l) forming means for breaking the seal and removing the sheath from about the cylinder, thereby allowing the cylinder to expand within the body cavity, blood vessel, or the like so as to contact the walls of said cavity, vessel, or the like with the outer surface of said foam cylinder at the target location, allowing the medicament to be absorbed by the wall of the patient's body

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5 cavity, blood vessel, or the like, while allowing
the patient's bodily fluids to freely flow
through the central lumen of said cylinder.

10 5 48. The method of claim 47 wherein the step of
forming a skin on at least the central lumen and end
surfaces of said cylinder comprises the step of forming
said cylinder by injecting foam into a mold such that the
15 foam forms a skin on all surfaces in direct contact with
the mold.

20 49. The method of claim 47 wherein the step of
forming a skin on at least the central lumen and end
surfaces of said cylinder comprises the steps of:
15 m) forming said cylinder by means of extruding a foam
material with a skin on the inside surface of the
25 central lumen; and
n) coating the end surfaces of the cylinder with a
hydrophillic gel which occludes the foam cells
20 when hydrated.

30 50. The method of claim 47 wherein the step of
forming a skin on at least the central lumen and end
surfaces of said cylinder comprises the steps of:
35 25 o) forming said cylinder by means of extruding a foam
material with a skin on the inside surface of the
central lumen; and
40 p) coating the end surfaces of the cylinder with a
material to form a skin.

30 51. The method of claim 47 wherein the step of
forming a skin on at least the central lumen and end
surfaces of said cylinder comprises the steps of:
45 q) forming a foam cylinder without a skin; and
35 r) bonding a skin onto the surface of said foam

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5 cylinder.

10 52. The method of claim 51 wherein the step of bonding a skin onto the surface of said foam cylinder comprises the step of dipping said cylinder so as to coat selected surfaces with a liquid material which cures and becomes a skin.

15 53. The method of claim 51 wherein the step of bonding a skin onto the surface of said foam cylinder comprises the step of dipping a cylindrically shaped skin material into a liquid foam material to thereby form the foam cylinder upon the preformed skin.

20 54. The method of claim 51 wherein the step of bonding a skin onto the surface of said foam cylinder comprises the step of spraying a skin forming material upon the surface of the cylinder.

25 55. The method of claim 54, further comprising the steps of:
30 s) inverting the foam cylinder before spraying the skin forming material thereon so as to expose the central lumen portion of the cylinder; and
35 25 t) re-inverting said cylinder following application of the skin so that the skin coated portion resumes its position as the surface of the central lumen of the cylinder.

40 56. The method of claim 47, further comprising the step of forming the ends of the cylinder into convoluted conical lips which compress inwardly so as to facilitate a seal between the end surfaces of the foam cylinder and an irregularly shaped body cavity.

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5 57. The method of claim 47, further comprising the
step of forming the ends of the cylinder into cylindrical
elastic lips which compress inwardly so as to facilitate a
10 5 seal between the end surfaces of the foam cylinder and an
irregularly shaped body cavity.

15 58. The method of claim 47, further comprising the
step of forming ends of the cylinder into a plurality of
petal-shaped lips which compress inwardly so as to
10 10 facilitate a seal between the end surfaces of the foam
cylinder and an irregularly shaped body cavity.

20 59. The method of claim 47, further comprising the
step of coating the ends of the foam cylinder with a
15 15 hydrophillic gel which occludes the foam cells when
hydrated so as to facilitate a seal between the end
25 25 surfaces of the foam cylinder and the body cavity.

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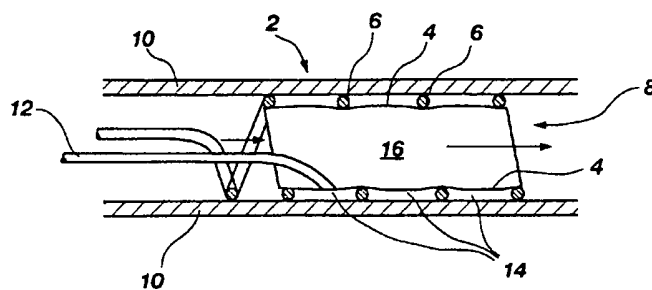
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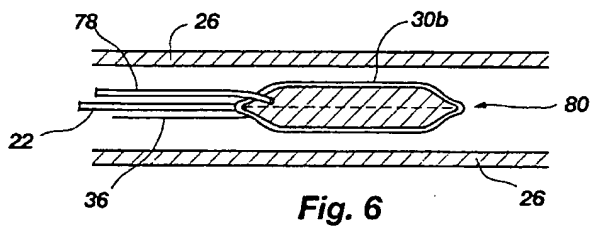
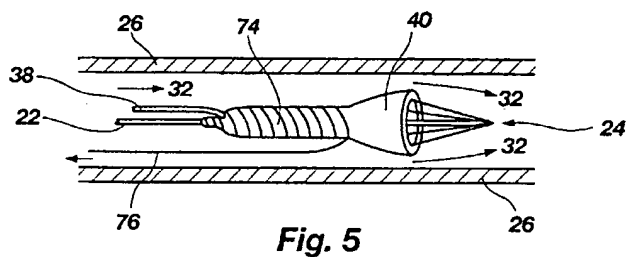
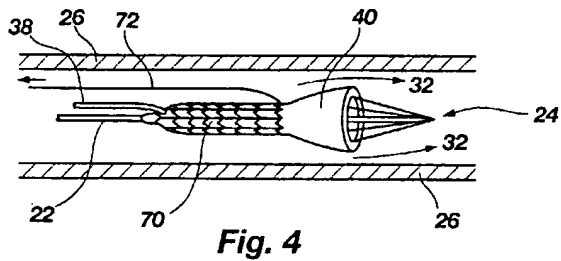
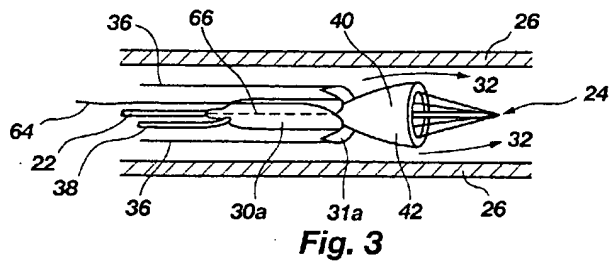
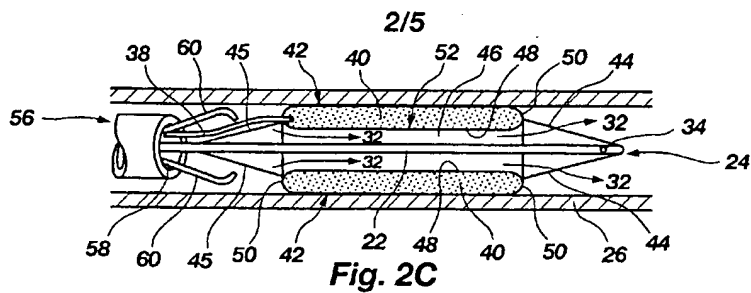
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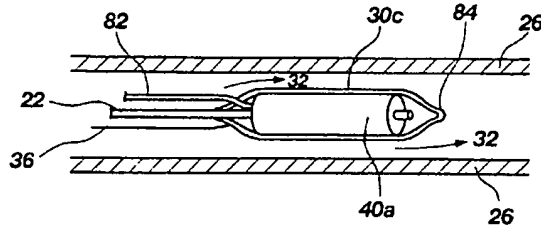


Fig. 7A

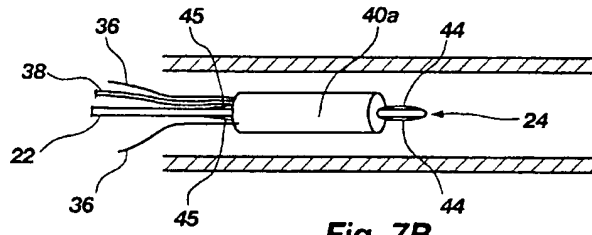


Fig. 7B

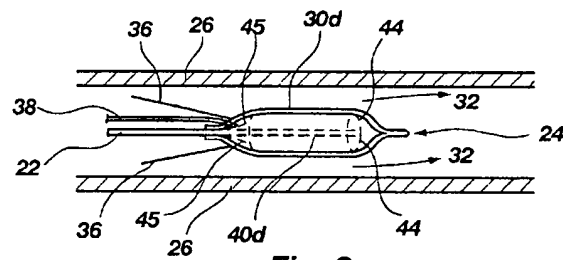


Fig. 8

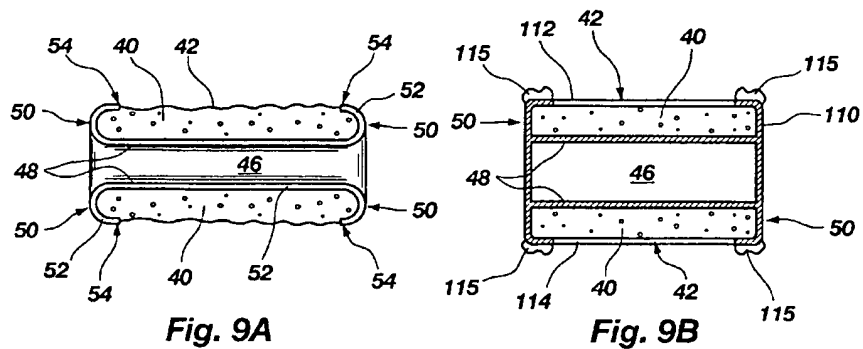


Fig. 9A

Fig. 9B

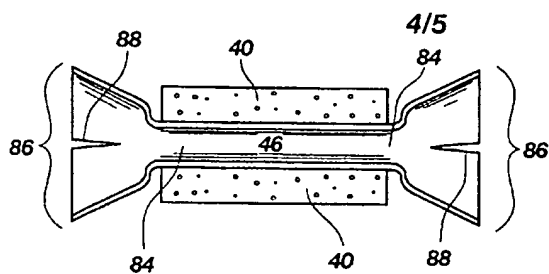


Fig. 10A

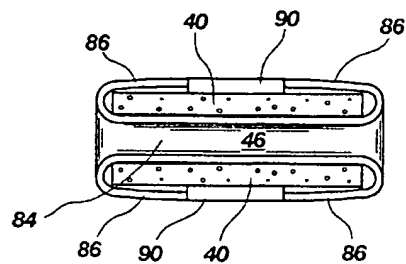


Fig. 10B

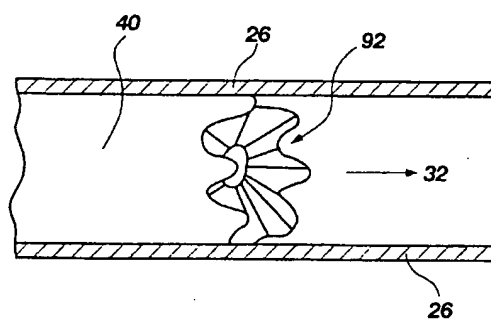


Fig. 11

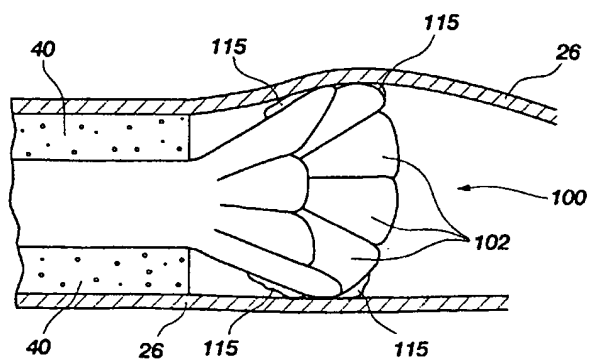


Fig. 12

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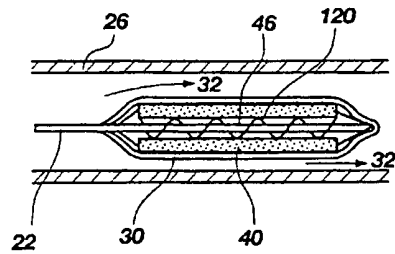


Fig. 13A

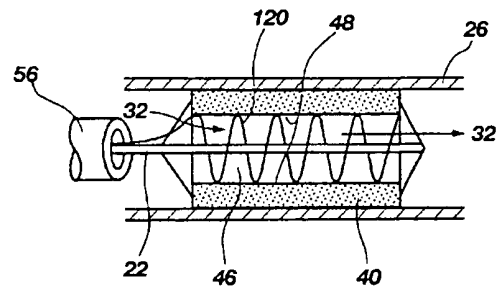


Fig. 13B

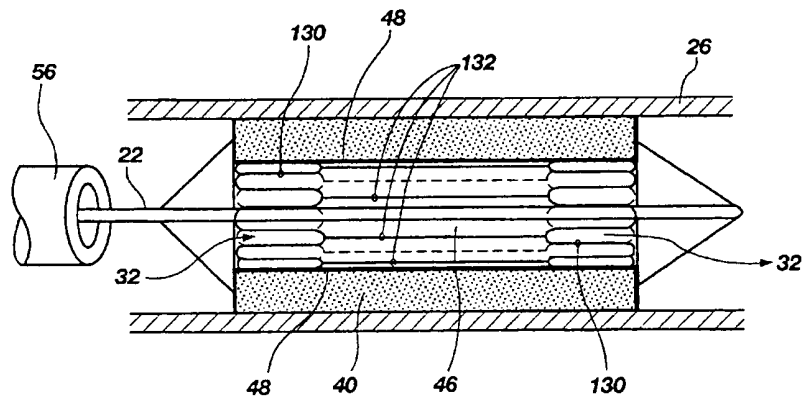


Fig. 14

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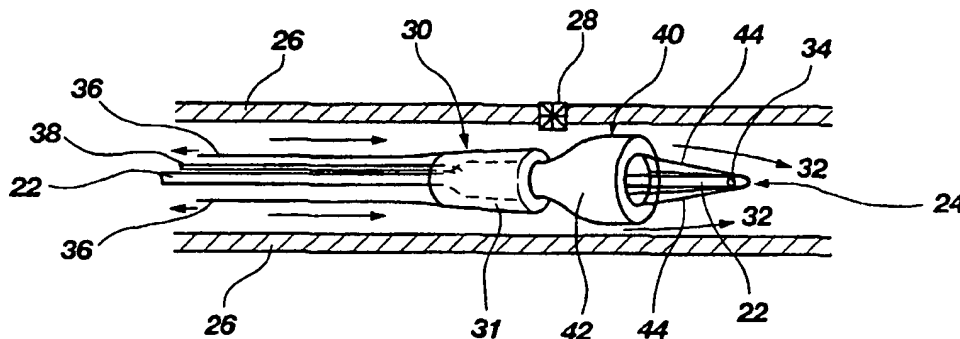
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(54) Title: APPARATUS AND METHOD FOR SELECTIVELY DELIVERING MEDICATION TO A WALL SECTION OF A BODY CAVITY, BLOOD VESSEL, OR THE LIKE



(57) Abstract: An apparatus (20) and method for selectively delivering a medicament to a target location (28) of the wall of a body cavity, blood vessel (26), or the like, comprising a compressed hollow cylinder (40) of permeable, expandable foam, attached to the distal end (24) of a delivery device (22) such as a catheter or catheter guidewire. Using the delivery device (22), the compressed cylinder (40) is advanced to a target location (28) within the body, and the compressed foam cylinder (40) is allowed to expand so as to contact the walls of the body cavity, blood vessel (26), or the like, while allowing bodily fluids (32) to freely flow through the central lumen (46) of the cylinder (40). The foam cylinder (40) is provided with means (38) for perfusing it with a medicament so that the medicament is placed in contact with the walls of the patient's anatomy, and is also provided with means for preventing the medicament from entering the patient's bloodstream.

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INTERNATIONAL SEARCH REPORT

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PCT/US00/03970

A. CLASSIFICATION OF SUBJECT MATTER

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Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/890.1, 891.1, 11-15, 18, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,599,292 A (YOON) 4 February 1997, entire document.	1-4, 7, 8, 10-14, 22-34, 41, 42, 44- 46 ----- 35-39, 47-59

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